

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
21 March 2002 (21.03.2002)

PCT

(10) International Publication Number
WO 02/22199 A2

(51) International Patent Classification⁷: **A61M 31/00**

(21) International Application Number: **PCT/US01/28544**

(22) International Filing Date:
11 September 2001 (11.09.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09/659,806 11 September 2000 (11.09.2000) US

(71) Applicant (for all designated States except US): **SOLUTIONS FOR VASCULAR INTERVENTION [US/US];**
62 Algonquin Trail Place, Ashland, MA 01721 (US).

(72) Inventor; and

(75) Inventor/Applicant (for US only): **PARODI, Juan, C.**
[AR/AR]; Mercedes 4255, Buenos Aires, Argentina (AR).

(74) Agent: **TOBOR, Ben, D.;** Bracewell & Patterson, L.L.P.,
P.O. Box 61389, Houston, TX 77208-1389 (US).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

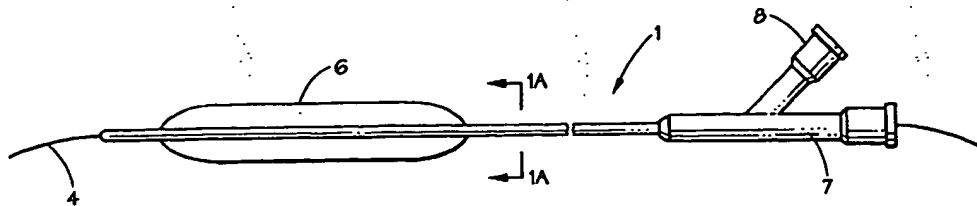
(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— without international search report and to be republished upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: **METHOD AND DEVICE TO DO ARTERIOGRAPHIES AND ANGIOGRAPHIES WITH A BALLOON WITHOUT INJECTING CONTRAST MEDIA IN THE VESSEL LUMEN**



(57) Abstract: A device for arteriographies and angiographies includes a catheter having an inflatable, elastimeric, and soft diagnosis balloon, which may be inflated with a contrast media, with the diagnosis balloon having an inflated shape which copies, but does not deform, the inner surface of a narrowed portion of an artery. The narrowed portion of the artery may be angiographed or arteriographed while the diagnosis balloon is inflated and copies the inner surface of the narrowed portion of the artery.

**METHOD AND DEVICE TO DO ARTERIOGRAPHIES AND
ANGIOGRAPHIES WITH A BALLON WITHOUT INJECTING
CONTRAST MEDIA IN THE VESSEL LUMEN**

RELATED APPLICATION

This application is a continuation-in-part application of Application Serial No. 08/751,909, filed November 18, 1996, entitled "Device and Method to do Arteriographies and Angioplasties With a Balloon and Without Injecting a Contrast Media in the Vessel Lumen", now U.S. Patent No. 6,117,124.

FIELD OF THE INVENTION

The present invention relates to the angioplasty techniques as well as to tests on arteries having narrowed or occluded portions and more particularly to a device and a method to do arteriographies and angioplasties avoiding the injection of a contrasting medium in the vessel lumen.

DESCRIPTION OF THE RELATED ART

The use of techniques availing of a catheter that includes a balloon to repair artery stenoses are known in the prior art. Stenosis and artery blockage decrease the nourishing flow that reaches the tissues irrigated by the affected artery. Tissue disorder caused by a decrease in irrigation may vary from necrosis of tissue to functional disorders caused by the decrease in the said flow. Sometimes, secondary arteries balance the blockage of the main artery. Whenever the narrowing of the artery is treated due to the consequences of flow decrease, it should be decided whether to resort to surgery or to the dilation of the artery by making use of a balloon.

SUMMARY OF THE INVENTION

Therefore, it is an object of the present invention to provide a new device and a method to do arteriographies, allowing for the simultaneous angioplasties as by inserting a catheter and a balloon capable of copying the narrowed portion of the artery under study and providing for the contrast required to view the artery, by utilizing a contrasting medium which is circumscribed within the balloon and which is not in relationship with the patient's tissue. Therefore, it is an object of the present

1 invention to provide a device to do arteriographies and angioplasties of the type that
2 uses a catheter wherein at least two passages are formed, first and second passage, the
3 first passage being utilized to run a guide wire, and which includes at least a first
4 inflatable, elastomeric and soft balloon that is in relationship with the second passage.
5 The latter configures a duct whereby an arteriographic contrasting medium is
6 introduced.

7 It is a further object of the present invention to provide a method to do
8 arteriographies and angioplasties, which method employs the device described above
9 and comprises the following steps: an artery is punctured remote of the stenoses or
10 occlusion, an introducer is inserted thus allowing for the passage of a catheter, at least
11 one of the balloons is moved until the narrowed portion of the artery is crossed over,
12 the balloon is placed all along the artery under study, the balloon is filled with an
13 arteriographic contrast substance at a very low pressure without deforming the
14 narrowing, the balloon is kept inflated, angiography tests are done and finally the
15 balloon is deflated.

16 BRIEF DESCRIPTION OF THE DRAWINGS

17 For further clarification and a better understanding of the object of the present
18 invention, numerous figures have been drawn depicting some of the preferred
19 embodiments of the present invention for purposes of illustration only, where:

20 FIG. 1 is a side view including a detail of the cross-sectional view of a catheter
21 in accordance with the device of the present invention;

22 FIG. 1A is a cross-sectional view taken along line 1A-1A of FIG. 1;

23 FIG. 2 is a view similar to FIG. 1 of another embodiment of the device of the
24 present invention;

25 FIG. 2A is a cross-sectional view taken along line 2A-2A of FIG. 2;

26 FIG. 3 is a view similar to FIG. 1 of another embodiment of the device of the
27 present invention;

28 FIG. 3A is a cross-sectional view taken along line 3A-3A of FIG. 3;

29 FIG. 4 is a view similar to FIG. 1 of another embodiment of the device of the
30 present invention;

31 FIG. 4A is a cross-sectional view taken along line 4A-4A of FIG. 4; and,

1 FIGS. 5 to 8 show the stages of a preferred embodiment of the present
2 invention.

3 DESCRIPTION OF THE PREFERRED EMBODIMENTS

4 As shown in FIG. 1, a catheter 1 is provided, the cross-sectional view of which
5 in detail shows a first passage 2 that allows a guide wire 4 to run along the shaft 5 of
6 the catheter, also providing a second passage 3 whereby the first elastomeric, thin
7 walled and resistant, low profile diagnosis balloon 6 is inflated. The material used for
8 the said balloon may be latex, silicone, polyurethane or any other appropriate and
9 elastomeric material whatsoever. The guide wire 4 as well as the balloon 6 may be
10 operated via operation means 7 and 8. Pursuant to the present invention, the balloon 6
11 is carried up to the narrowed portion of the artery, as detailed when referring to FIGS.
12 5 to 8, and filled with an appropriate contrast media, such as a radiopaque substance.
13 The balloon has a very thin but resistant wall, which, upon inflation, takes exactly the
14 same form of the artery inner surface (luminogram) without deforming same. The
15 balloon 6 shall have the length required to view the desired portion of the artery.
16 Amongst the main features, the balloon may be inflated at a very low pressure thus
17 not altering, as stated above, the contour of the artery under study. This device allows
18 a guide wire to run along the artery lumen. Owing to the fact that the balloon has a
19 very low profile, same allows for the introduction thereof in the narrowed or occluded
20 portion of the artery, which portion is crossed over by the guide wire. The balloon 6
21 may be inflated at pressure of 1 to 3 atmospheres, and preferably at a pressure of
22 approximately 2 atmospheres.

23 Diagnosis balloon 6, as previously described, can be formed of a variety of
24 elastomeric materials such as silicone, latex, or polyurethane. The elastomeric
25 materials from which the diagnosis balloon 6 may be made are preferably ultra
26 compliant, whereby they are capable of stretching, or expanding, up to more than
27 500% from their relaxed, or unstretched, state. These diagnosis balloons 6, when
28 inflated, as previously discussed, are capable of copying, or conforming to, the shape
29 of the vessel, or artery, interior, without expanding or distending the artery, or vessel,
30 itself. Preferably, the material from which the diagnosis balloon is made, has an
31 elongation property (percentage), before breaking, of from approximately 500% to

1 2,000% and preferably within the range of from approximately 800% to 1200%.
2 Examples of a suitable material for the manufacture of the diagnosis balloons are
3 silicone elastomers, such as models MED-4120 and MED-4020, of NuSil Technology
4 of Carpinteria, California. These elastomers have elongation properties of 1100%
5 and 1000%.

6 Once the luminogram is obtained by injecting the contrasting medium in the
7 balloon, dilation of the narrowing may then proceed by using a second expanding
8 balloon located upon the catheter that carries the diagnosis balloon, as shown in the
9 three embodiments of the present invention illustrated in FIGS. 2, 3, and 4.

10 The catheter 1a in FIG. 2 has a first passage 9 for the guide wire 4a to run, a
11 second passage 10 that allows inflation of the diagnosis balloon 6a, similar to balloon
12 6 in FIG. 1 and a third passage 11 permitting the expansion of the angioplasty balloon
13 12, located behind the diagnosis balloon 6a.

14 Catheter 1b in FIG. 3 includes a first passage 13 for the guide wire 4b to run
15 and a second passage 14 which allows the diagnosis balloon 6b to be inflated, which
16 balloon is similar to balloons 6 and 6a; said catheter also includes a container that
17 shelters a therapeutic or angioplasty balloon 12'. The diagnosis balloon 6b carries the
18 therapeutic balloon 12' within its lumen. The therapeutic balloon 12' runs on the wire
19 4b and provides consistency to the diagnosis balloon 6b.

20 Catheter 1c illustrated in FIG. 4 is similar to the one depicted in FIG. 3, but
21 the therapeutic balloon 12'' is fixed within the diagnosis balloon 6c anchored to the
22 shaft of the catheter 1c, thus a third passage 15 is provided for such purpose.

23 The second balloons 12, 12' and 12'' of the different embodiments of the
24 present invention differ from diagnosis balloons 6 to 6c in that the former are not
25 elastomeric for the purpose of achieving a great radial force allowing for the dilation
26 of the narrowed artery. The angioplasty balloon shall have a low profile and shall be
27 inflated through an independent passage of the catheter, as illustrated in the case of
28 the three passages of the pertinent embodiments.

29 In the event the angioplasty balloon is sheltered inside the diagnosis balloon,
30 the latter shall enclose a tiny catheter which houses in turn, a guide wire and said
31 catheter shall act as a rail on which the second balloon is run, and which shall be

1 suitably located to proceed to the dilation of the artery narrowing. The second balloon
2 may be fixedly anchored and shall move jointly with the elastomeric balloon so as to
3 be placed in the right location to dilate the narrowed portion of the artery.

4 In accordance with another aspect of the present invention, diagnosis balloons
5 6, 6a, 6b, and/or 6c, may be coated or doped with a radiopaque substance, such as
6 barium, gold, platinum, or silver. Alternatively, such a radiopaque substance may be
7 mixed into the elastomeric material from which the diagnosis balloons are made. The
8 diagnosis balloons would thus be radiopaque, whereby the diagnosis balloon would
9 not need to be expanded by the introduction of a contrast substance, but could rather
10 be expanded with a non-radiopaque fluid, such as non-toxic gases, such as carbon
11 dioxide, or by liquids such as water or other non-toxic liquid mixtures. A radiopaque
12 diagnosis balloon could be utilized in conjunction with an angioplasty balloon such as
13 angioplasty balloons 12, 12' and/or 12'', as previously described. The foregoing
14 described radiopaque diagnosis balloons, whether used alone, or in conjunction with
15 an angioplasty balloon, may be inflated to conform to vessel, or artery, irregularities
16 and narrowing. It is believed that a radiopaque diagnosis balloon will be useful in
17 imaging ostial lesions, where a large vessel has branches, and where stenosis can
18 occur at the junction of two vessels. Again, as with a diagnosis balloon filled with a
19 contrast material, there is a significant clinical advantage since toxic radiopaque
20 contrast media need not come into contact with living tissue.

21 As regards another aspect of the present invention, a method is illustrated in
22 FIGS. 5 to 8, which method comprises the following steps: the artery is punctured and
23 a guide wire is introduced which crosses over narrowing or occlusion "E", as
24 illustrated in FIG. 5. This step is similar to any other angiographic procedure which
25 may include angioplasty or not. Subsequently, an introducer means of a suitable size
26 is placed to allow the introduction of a diagnosis-therapeutic catheter.

27 The device is moved forward until the narrowing "E" is crossed over, placing
28 the diagnosis balloon of the present invention all along the artery under study, as
29 illustrated in FIG. 6. The diagnosis balloon is filled with a contrasting substance at a
30 very low pressure and the balloon is kept dilated. The angiographic tests are
31 accurately done and the catheter is placed in the right angle and location so as to

1 achieve a better view of the narrowed portion of the artery.

2 Once the diagnosis is made, the elastomeric balloon is deflated and the
3 angioplasty balloon 12 is placed at the narrowing "E" level. Then, same is inflated for
4 the purpose of dilating the injured portion of the artery. The angioplasty balloon is
5 deflated and the diagnosis elastomeric balloon is affixed in the right position,
6 repeating the diagnosis steps for the purpose of confirming the effectiveness of the
7 artery dilation attained. Should dilation be suitable, the proceeding shall be deemed to
8 be finished; should dilation fail to be suitable, the proceeding shall be repeated. If the
9 correct results are not obtained, a balloon having a different diameter may be affixed
10 avoiding the initial system; a "stent" may alternatively be attached. For the purpose of
11 anchoring same, the very same non-elastomeric balloon that comprises the device may
12 be used or else, another balloon with different features may be employed.

13 If the diagnosis balloons 6, 6a, 6b, and/or 6c have been made radiopaque, as
14 previously described, the foregoing described method may also be conducted in the
15 same manner, except that it would not be necessary to fill the radiopaque diagnosis
16 balloon with a contrast substance. Of course, if desired, the radiopaque balloon could
17 be filled with a contrast substance at a very low pressure.

18 According to the method and the device of the present invention, many
19 advantages are gained, for instance: no contrasting medium needs to be injected in the
20 lumen of the vessel, thus avoiding pain, possible allergy development and renal
21 damage caused by the contrasting medium. Carbon dioxide may be alternatively used
22 to inflate the balloon, thus obtaining the digital image by contrast reduction and not
23 by contrast increase, as in the case of radiopaque substances. The advantage of
24 having carbon dioxide inside and not outside the balloon lies in that a permanent
25 image of the artery lumen is obtained, and several incidences may also be achieved
26 with no need for further gas inoculations. Whether by changing the location of the
27 whole device or of the non-elastomeric balloon, the angioplasty may be done without
28 changing the device and an x-ray check-up may be done simultaneously as by
29 inflating the elastomeric balloon again in order to confirm the effectiveness of the
30 dilation as regards reduction of artery narrowing. This procedure proves to be cost
31 efficient since the amount of contrasting substance injected as well as the time

1 consumed are reduced.

2 As the contrast media is not injected directly into the artery, substances
3 utilized do not need to be non-ionic. Both quality and volume of contrast media can
4 be a source of decreasing costs in addition to the advantages enumerated in relation to
5 decreasing risks to the patient.

1 I claim:

- 2 1. A device for doing an arteriography in a narrowed portion of an artery,
3 the artery having an inner surface, comprising:
4 a catheter having an inflatable, elastomeric diagnosis balloon, and a
5 first
6 passage in fluid communication with the diagnosis balloon;
7 the diagnosis balloon being formed of an ultra compliant material
8 having
9 an elongation property of between approximately 500% to
10 2000%;
11 the first passage being adapted to inflate the diagnosis balloon
12 with a contrast
13 media, the contrast media being circumscribed within the
14 diagnosis balloon and not in contact with the inner surface of
15 the artery;
16 the diagnosis balloon having a first uninflated shape for delivery of the
17 diagnosis balloon to a location within, and along, the narrowed
18 portion of the artery; and
19 the diagnosis balloon having a second inflated shape, after being
20 inflated with
21 the contrast media, the second inflated shape copying, and not
22 deforming, the inner surface of the artery in the narrowed
23 portion of the artery, whereby the diagnosis balloon and the
24 narrowed portion of the artery may be arteriographed while the
25 diagnosis balloon is in the second inflated shape.
- 26 2. The device of claim 1, including a second passage in the catheter for
27 passage of a guide wire therethrough.
- 28 3. The device of claim 1, including an angioplasty balloon located on the
29 catheter for dilating the narrowed portion of the artery.
- 30 4. The device of claim 3, wherein the diagnosis balloon is disposed
31 toward a distal end of the catheter, and the angioplasty balloon is

- 1 disposed adjacent the diagnosis balloon.
- 2 5. The device of claim 4, wherein the angioplasty balloon is disposed
3 inside the diagnosis balloon.
- 4 6. The device of claim 1, wherein the elongation property of the material
5 forming the diagnosis balloon is between approximately 800% and
6 1200%.
- 7 7. The device of claim 1, wherein the material forming the diagnosis
8 balloon is a silicone elastomer having an elongation property of
9 between approximately 1000% to 1100%.
- 10 8. A device for doing an angiography in a narrowed portion of an vessel,
11 the vessel having an inner surface, comprising:
12 a catheter having an inflatable, elastomeric diagnosis balloon,
13 and a first
14 passage in fluid communication with the diagnosis balloon;
15 the diagnosis balloon being formed of an ultra compliant
16 material having
17 an elongation property of between approximately 500%
18 to 2000%;
19 the first passage being adapted to inflate the diagnosis
20 balloon with
21 a contrast media, the contrast media being
22 circumscribed within the diagnosis balloon and not in
23 contact with the inner surface of the vessel;
24 the diagnosis balloon having a first uninflated shape for
25 delivery of the
26 diagnosis balloon to a location within, and along, the
27 narrowed portion of the vessel; and
28 the diagnosis balloon having a second inflated shape, after
29 being inflated with
30 the contrast media, the second inflated shape copying,
31 and not deforming, the inner surface of the vessel in the

1 narrowed portion of the vessel, whereby the diagnosis
2 balloon and the narrowed portion of the vessel may be
3 angiographed while the diagnosis balloon is in the
4 second inflated shape.

5 9. The device of claim 8, including a second passage in the catheter for
6 passage of a guide wire therethrough.

7 10. The device of claim 8, including an angioplasty balloon located on the
8 catheter for dilating the narrowed portion of the vessel.

9 11. The device of claim 10, wherein the diagnosis balloon is disposed
10 toward a distal end of the catheter, and the angioplasty balloon is
11 disposed adjacent the diagnosis balloon.

12 12. The device of claim 11, wherein the angioplasty balloon is disposed
13 inside the diagnosis balloon.

14 13. The device of claim 8, wherein the elongation property of the material
15 forming the diagnosis balloon is between approximately 800% and
16 1200%.

17 14. The device of claim 8, wherein the material forming the diagnosis
18 balloon is a silicone elastomer having an elongation property of
19 between approximately 1000% to 1100%.

20 15. A method for doing arteriographies in a portion of an artery having an
21 inner surface, comprising the steps of:

22 providing an expandable, elastomeric diagnosis balloon upon a
23 catheter, the

24 diagnosis balloon having an outer surface, and being
25 formed of an ultra compliant material having an
26 elongation property of between approximately 500% to
27 2000%;

28 introducing the diagnosis balloon into the portion of the
29 artery to be arteriographed;

30 filling the diagnosis balloon with a contrast medium to inflate
31 the diagnosis balloon until the outer surface of the

1 diagnosis balloon conforms to the inner surface of the
2 portion of the artery to be arteriographed, without
3 deforming the inner surface of the portion of the artery
4 to be arteriographed; and
5 imaging the inflated diagnosis balloon and the portion of the
6 artery to the arteriographed.

7 16. The method of claim 15, including the steps of deflating the diagnosis
8 balloon and removing the diagnosis balloon from the artery.

9 17. The method of claim 15, including the step of inflating the diagnosis
10 balloon at a low pressure.

11 18. The method of claim 15, including the step of utilizing a radiopaque
12 substance as the contrast medium.

13 19. The method of claim 15, including the step of utilizing a radiolucent
14 substance as the contrast medium.

15 20. The method of claim 19, wherein the contrast medium is carbon
16 dioxide.

17 21. The method of claim 15, including the steps of:
18 providing an angioplasty balloon upon the catheter; and
19 after the diagnosis balloon and the portion of the artery to be
20 arteriographed are imaged, inflating the angioplasty balloon to
21 dilate the portion of the artery which was imaged.

22 22. The method of claim 21, including the step of deflating the angioplasty
23 balloon and removing the angioplasty balloon from the artery.

24 23. The method of claim 22, including the steps of:
25 after the portion of the artery has been dilated, placing the diagnosis
26 balloon within the portion of the artery which was dilated by
27 the angioplasty balloon;
28 filling the diagnosis balloon with a contrast medium to inflate the
29 diagnosis balloon
30 until the outer surface of the diagnosis balloon conforms to the
31 inner surface of the portion of the artery which had been

- 1 dilated; and
2 imaging the diagnosis balloon and the portion of the artery which had
3 been dilated.
- 4 24. The method of claim 21, including the step of providing the
5 angioplasty balloon upon the catheter, by disposing the angioplasty balloon within the
6 diagnosis balloon.
- 7 25. The method of claim 15, including the step of forming the diagnosis
8 balloon from a material having an elongation property between
9 approximately 800% and 1200%.
- 10 26. The method of claim 15, including the step of forming the diagnosis
11 balloon from a silicone elastomer having an elongation property of
12 between approximately 1000% to 1100%.
- 13 27. A method for doing angiographies in a portion of a vessel having an
14 inner surface, comprising the steps of:
15 providing an expandable, elastomeric diagnosis balloon upon a
16 catheter, the diagnosis balloon having an outer surface and
17 being formed of an ultra compliant material having an
18 elongation property of between approximately 500% to 2000%;
19 introducing the diagnosis balloon into the portion of the vessel to be
20 angiographed;
21 filling the diagnosis balloon with a contrast medium to inflate the
22 diagnosis balloon until the outer surface of the diagnosis
23 balloon conforms to the inner surface of the portion of the
24 vessel to be angiographed, without deforming the inner surface
25 of the portion of the vessel to be angiographed; and
26 imaging the inflated diagnosis balloon and the portion of the vessel to
27 the angiographed.
- 28 28. The method of claim 27, including the steps of deflating the diagnosis
29 balloon and removing the diagnosis balloon from the artery.
- 30 29. The method of claim 27, including the step of inflating the diagnosis
31 balloon at a low pressure.

- 1 30. The method of claim 27, including the step of utilizing a radiopaque
2 substance as the contrast medium.
- 3 31. The method of claim 27, including the step of utilizing a radiolucent
4 substance as the contrast medium.
- 5 32. The method of claim 31, wherein the contrast medium is carbon
6 dioxide.
- 7 33. The method of claim 27, including the steps of:
8 providing an angioplasty balloon upon the catheter; and
9 after the diagnosis balloon and the portion of the vessel to be
10 angiographed are imaged, inflating the angioplasty balloon to
11 dilate the portion of the vessel which was imaged.
- 12 34. The method of claim 33, including the step of deflating the angioplasty
13 balloon and removing the angioplasty balloon from the artery.
- 14 35. The method of claim 34, including the steps of:
15 after the portion of the vessel has been dilated, placing the diagnosis
16 balloon within the portion of the vessel which was dilated by
17 the angioplasty balloon;
18 filling the diagnosis balloon with a contrast medium to inflate the
19 diagnosis balloon until the outer surface of the diagnosis
20 balloon conforms to the inner surface of the portion of the
21 vessel which had been dilated; and
22 imaging the diagnosis balloon and the portion of the vessel which had
23 been dilated.
- 24 36. The method of claim 33, including the step of providing the
25 angioplasty balloon upon the catheter, by disposing the angioplasty balloon within the
26 diagnosis balloon.
- 27 37. The method of claim 27, including the step of forming the diagnosis
28 balloon from a material having an elongation property between
29 approximately 800% and 1200%.
- 30 38. The method of claim 27, including the step of forming the diagnosis

1 balloon from a silicone elastomer having an elongation property of
2 between approximately 1000% to 1100%.

3 39. A method for doing arteriographies in a portion of an artery having an
4 inner surface, comprising the steps of:

5 providing an expandable, radiopaque elastomeric diagnosis balloon upon a
6 catheter, the radiopaque diagnosis balloon having an outer surface;
7 introducing the radiopaque diagnosis balloon into the portion of the
8 artery to be arteriographed;
9 filling the radiopaque diagnosis balloon with a fluid to inflate the
10 radiopaque diagnosis balloon until the outer surface of the
11 radiopaque diagnosis balloon conforms to the inner surface of
12 the portion of the artery to be arteriographed, without
13 deforming the inner surface of the portion of the artery to be
14 arteriographed; and
15 imaging the inflated radiopaque diagnosis balloon and the portion of
16 the artery to be arteriographed.

17 40. The method of claim 39, including the steps of deflating the
18 radiopaque diagnosis balloon and removing the radiopaque diagnosis balloon from the
19 artery.

20 41. The method of claim 39, including the step of inflating the radiopaque
21 diagnosis balloon at a low pressure.

22 42. The method of claim 39, including the step of utilizing a non-toxic gas
23 as the fluid.

24 43. The method of claim 39, including the step of utilizing a non-toxic
25 liquid as the fluid.

26 44. The method of claim 43, wherein the fluid is carbon dioxide.

27 45. The method of claim 39, including the steps of:

28 providing an angioplasty balloon upon the catheter; and

29 after the radiopaque diagnosis balloon and the portion of the artery to
30 be arteriographed are imaged, inflating the angioplasty balloon
31 to dilate the portion of the artery which was imaged.

1 46. The method of claim 45, including the step of deflating the angioplasty
2 balloon and removing the angioplasty balloon from the artery.

3 47. The method of claim 46, including the steps of:
4 after the portion of the artery has been dilated, placing the radiopaque
5 diagnosis balloon within the portion of the artery which was
6 dilated by the angioplasty balloon;
7 filling the radiopaque diagnosis balloon with a fluid to inflate the
8 radiopaque diagnosis balloon until the outer surface of the
9 radiopaque diagnosis balloon conforms to the inner surface of
10 the portion of the artery which had been dilated; and
11 imaging the radiopaque diagnosis balloon and the portion of the artery
12 which had been dilated.

13 48. The method of claim 45, including the step of providing the
14 angioplasty balloon upon the catheter, by disposing the angioplasty balloon within the
15 radiopaque diagnosis balloon.

16 49. The method of claim 39, including the step of forming the radiopaque
17 diagnosis balloon from an ultra compliant material having an elongation property of
18 between approximately 500% to 2000%.

19 50. The method of claim 39, including the step of forming the radiopaque
20 diagnosis balloon from an ultra compliant material having an elongation property of
21 between approximately 800% to 1200%.

22 51. The method of claim 39, including the step of forming the radiopaque
23 diagnosis balloon from a silicone elastomer having an elongation property of between
24 approximately 1000% to 1100%.

25 52. A method for doing angiographies in a portion of a vessel having an
26 inner surface, comprising the steps of:

27 providing an expandable, elastomeric radiopaque diagnosis balloon upon a
28 catheter, the radiopaque diagnosis balloon having an outer surface;
29 introducing the radiopaque diagnosis balloon into the portion of the
30 vessel to be angiographed;
31 filling the radiopaque diagnosis balloon with a fluid to inflate the

1 radiopaque diagnosis balloon until the outer surface of the
2 radiopaque diagnosis balloon conforms to the inner surface of
3 the portion of the vessel to be angiographed, without deforming
4 the inner surface of the portion of the vessel to be
5 angiographed; and

6 imaging the radiopaque inflated diagnosis balloon and the portion of
7 the vessel to the angiographed.

8 53. The method of claim 52, including the steps of deflating the
9 radiopaque diagnosis balloon and removing the radiopaque diagnosis balloon from the
10 artery.

11 54. The method of claim 52, including the step of inflating the radiopaque
12 diagnosis balloon at a low pressure.

13 55. The method of claim 52, including the step of utilizing a non-toxic gas
14 as the fluid.

15 56. The method of claim 52, including the step of utilizing a non-toxic
16 liquid as the fluid.

17 57. The method of claim 56, wherein the fluid is carbon dioxide.

18 58. The method of claim 52, including the steps of:
19 providing an angioplasty balloon upon the catheter; and
20 after the radiopaque diagnosis balloon and the portion of the vessel to
21 be angiographed are imaged, inflating the angioplasty balloon
22 to dilate the portion of the vessel which was imaged.

23 59. The method of claim 58, including the step of deflating the angioplasty
24 balloon and removing the angioplasty balloon from the vessel.

25 60. The method of claim 59, including the steps of:
26 after the portion of the vessel has been dilated, placing the radiopaque
27 diagnosis balloon within the portion of the vessel which was
28 dilated by the angioplasty balloon;
29 filling the radiopaque diagnosis balloon with a fluid to inflate the
30 radiopaque diagnosis balloon until the outer surface of the
31 radiopaque diagnosis balloon conforms to the inner surface of

1 the portion of the vessel which had been dilated; and
2 imaging the radiopaque diagnosis balloon and the portion of the vessel
3 which had been dilated.

4 61. The method of claim 58, including the step of providing the
5 angioplasty balloon upon the catheter, by disposing the angioplasty balloon within the
6 radiopaque diagnosis balloon.

7 62. The method of claim 52, including the step of forming the radiopaque
8 diagnosis balloon from an ultra compliant material having an elongation property of
9 between approximately 500% to 2000%.

10 63. The method of claim 52, including the step of forming the radiopaque
11 diagnosis balloon from an ultra compliant material having an elongation property of
12 between approximately 800% to 1200%.

13 64. The method of claim 52, including the step of forming the radiopaque
14 diagnosis balloon from a silicone elastomer having an elongation property of between
15 approximately 1000% to 1100%.

